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| APPLICATION NO.                        | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-----------------|----------------------|-------------------------|------------------|
| 10/087,563                             | 02/28/2002      | Alberto Siccardi     | 113957-260              | 5126             |
| 5                                      | 7590 07/25/2003 | William . Mar        |                         |                  |
| BELL BOYD & LLOYD LLC                  |                 |                      | EXAMINER                |                  |
| P O BOX 1135<br>CHICAGO, IL 60690-1135 |                 |                      | HARMON, CHR             | ISTOPHER R       |
|  |                 | •                    | ART UNIT                | PAPER NUMBER     |
|  |                 |                      | 3721                    | 12               |
|  |                 |                      | DATE MAILED: 07/25/2003 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| _  |   |   |                      |  |  |
|--|---|---|----------------------|--|--|
|  | Application No.   | Applicant(s)  |                      |  |  |
| ,  | 10/087,563  | SICCARDI, ALBERTO   |                      |  |  |
| Office Action Summary  | Examiner  | Art Unit  |                      |  |  |
|  | Christopher R Harmon  | 3721  |                      |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the  | correspondence ac   | ldress               |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status | 36(a). In no event, however, may a reply be ti<br>y within the statutory minimum of thirty (30) da<br>vill apply and will expire SIX (6) MONTHS fron<br>, cause the application to become ABANDON | mely filed  ys will be considered time in the mailing date of this of ED (35 U.S.C. § 133). | ly.<br>ommunication. |  |  |
| 1) Responsive to communication(s) filed on 24 2  | <u>lune 2003</u> .  |   |                      |  |  |
| 2a)☐ This action is <b>FINAL</b> . 2b)☒ Th   | is action is non-final.   |   |                      |  |  |
| 3) Since this application is in condition for allows   |   |   | ne merits is         |  |  |
| closed in accordance with the practice under <b>Disposition of Claims</b>  | Ex parte Quayle, 1935 C.D. 11,  | 453 O.G. 213.   |                      |  |  |
| 4) Claim(s) 16-50 is/are pending in the application  | on.   |   |                      |  |  |
| 4a) Of the above claim(s) 39-50 is/are withdraw  | vn from consideration.  |   |                      |  |  |
| 5) Claim(s) is/are allowed.  |   |   |                      |  |  |
| 6)⊠ Claim(s) <u>16-38</u> is/are rejected.   |   |   |                      |  |  |
| 7) Claim(s) is/are objected to.  |   |   |                      |  |  |
| 8) Claim(s) are subject to restriction and/o   | r election requirement.   |   |                      |  |  |
| Application Papers   |   |   |                      |  |  |
| 9) The specification is objected to by the Examine   |   |   |                      |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accep   |   |   |                      |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |   |                      |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.   |   |   |                      |  |  |
| If approved, corrected drawings are required in reply to this Office action.   |   |   |                      |  |  |
| 12) The oath or declaration is objected to by the Ex   | ammer.  |   |                      |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  |   |   |                      |  |  |
| 13) Acknowledgment is made of a claim for foreign  | n priority under 35 U.S.C. § 119(   | a)-(d) or (f).  |                      |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |   |   |                      |  |  |
| 1. Certified copies of the priority document   |   |   |                      |  |  |
| 2. Certified copies of the priority document   | • •   |   |                      |  |  |
| <ul> <li>3. Copies of the certified copies of the prior</li> <li>application from the International Bu</li> <li>* See the attached detailed Office action for a list</li> </ul>  | reau (PCT Rule 17.2(a)).  |   | Stage                |  |  |
| 14)☐ Acknowledgment is made of a claim for domesti   | c priority under 35 U.S.C. § 119(   | e) (to a provisiona   | l application).      |  |  |
| <ul> <li>a) ☐ The translation of the foreign language pro</li> <li>15)☒ Acknowledgment is made of a claim for domest</li> </ul>  | * *   |   |                      |  |  |
| Attachment(s)  | - 7   |   |                      |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1  | 5) 🔲 Notice of Informal   | y (PTO-413) Paper No<br>Patent Application (PT  |                      |  |  |
| J.S. Patent and Trademark Office   |   | <del></del> <u>-</u>  |                      |  |  |



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### **DETAILED ACTION**

# Request for Continued Examination

 The Request for Continued Examination filed on 6/24/03 (RCE) under 37 CFR 1.114 based on parent Application No. 10/087,563 is acceptable and a RCE has been established. An action on the RCE follows.

### Election/Restrictions

2. Applicant's election with traverse of claims 16-38 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that there is no serious burden on the Examiner. This is not found persuasive because the withdrawn claims are directed towards divergent subject matter as stated in paper no. 8.

The requirement is still deemed proper and is therefore made FINAL.

#### Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 16-17, 24, 27, 30-32, 34, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Ivey (US 5,976,299).

Baldini et al. teach a method for the manufacture and fillings of flexible sterilizable bags comprising printing 2, cleaning 3, and sterilizing of a film 4; aligns the



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film 4d; welding the film to form a bag 5; welding a valve to the film bag 5b; dosing the bag DOS; filling the bag STO; (figure 2).

In operation, the system forms, sterilizes, fills, and seals printed flexible bags with valves attached. Because the applicant is one of the common inventors of US Patent 4,656,813, the invention and its operation are not discussed here, rather only the improvements upon the invention as understood by the examiner. Baldini et al. do not describe certain limitations claimed by the applicant as improvements upon the commonly owned invention; such as dry cleaning the printed film, humidifying the valve cavity, or using control algorithms for shaping and welding the bags.

Ivey teaches a dry cleaning procedure of a packaging film with purified air. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the dry cleaning procedure as taught by Fabricius in the invention of Baldini et al. in order to free the packaging film of foreign substances.

5. Claims 18-20, 28-29, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Ivey (US 5,976,299) as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Duffey et al. (US 5,129,212).

The modified invention of Baldini et al. does not indicate sterilizing the spouts prior to application to the flexible bag material. Duffey et al. teach a method and apparatus for automatically filling and sterilizing containers in which spouts S are moved



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along tunnel 122 and sterilized by hydrogen peroxide gaseous medium (column 10, line 7 - column 11, line 33; figures 10-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to sterilize the spouts prior to applying them to the bag material as taught by Duffey et al. in the modified invention of Baldini et al. in order to maintain a sterile environment throughout the bag manufacturing procedure.

The modified invention of Baldini et al. does not indicate a contribution regulation valve, a constant pressure valve, and a flowmeter. It would have been obvious to one of ordinary skill in the art to include a constant pressure valve for adjusting/regulating the pressure of the system as is well known in the art.

Duffey et al. teach a volume flow meter (not shown) and contribution regulation valve (single head filler valve) 186 operating in a pressurized system (column 13, lines 1-12). A predetermined amount of filling liquid is supplied to the bags accurately.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the flowmeter and valve as taught by Duffey et al. in the modified invention of Baldini et al. to accurately fill the bags.

6. Claims 21-22, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Ivey, and Duffey et al. as applied to claims 18-20, 28-29, and 35 above and further in view of Madsen (US 3,451,403).

The modified invention of Baldini et al., in both instances above, does not disclose detecting electric conductability of the sanitizing solution. Madsen teaches a method

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and apparatus for determining the purity of a flowing solution or mixture in which "A stream of the solution or mixture is fed into a container after which a diluting or concentrating agent is fed into the container, and measuring means continuously measures the conductivity of the contents of the container." (abstract of the disclosure, lines 3-7). Automatic control means are provided "to switch the feed back to the solution or mixture when the conductivity has declined to a predetermined value..." (abstract of the disclosure, lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include a system as described by Madsen in either modified invention of Baldini et al. in order to monitor and control the amount of solution being administered to each bag.

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. in view of Ivey, as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Ogata (GB 2142282 A).

The modified invention of Baldini et al. does not disclose a "heated" printing procedure. Ogata (GB 2142282 A) teaches an automatic packing machine in which " a heated type is pressed against the receiving roll through the packing sheet and printing tape and packing sheet to apply printing to the packing sheet" (claim 1, lines 6-9). It would have been obvious to one of ordinary skill in the art to include the heated printing procedure in the modified invention of Baldini et al. in order to apply printing to the bag material.

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8. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. in view of Ivey as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Brennan et al. (US 4,587,793).

Regarding the limitation of a suspension ring, modified Baldini et al. do not provide for this feature. Brennan et al. (US 4,587,793) teach a bag with a suspension aperture 178 (figure 7) providing for hanging of the bag during the infusion process (column 8, lines 53-54). It would have been obvious to one of ordinary skill in the art, at the time of the invention, to include the suspension aperture as taught by Brennan et al. in the modified invention of Baldini et al. in order to support the bag during the infusion process.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al.
 (US 4,656,813) in view of Ivey as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Aindow et al. (US 5,934,043).

The modified invention of Baldini et al. provides a ultrasonic welder 21 but does not disclose specifically a piezoelectric transducer, sonotrode, etc. as in claim 45. Aindow et al. teach a web cutting apparatus comprising a ultrasonically vibrated anvil 12 (sonotrode); position transducers 40; and piezoelectric core 142 (figures 5 and 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the various welding elements as taught by Aindow et al. in the modified invention of Baldini et al. in order to seal the web.

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## Response to Arguments

10. Applicant's arguments with respect to claims 16-38 have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R Harmon whose telephone number is 703-308-8643. The examiner can normally be reached on Monday-Thursday from 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 703-308-2187. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

ch July 21, 2003

> EUGENE KIM PRIMARY EXAMINER

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